

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION III 1650 Arch Street Philadelphia, Pennsylvania 19103-2029

DEC 1 7 1909

The Honorable Jane T. Nishida Secretary Maryland Department of the Environment 2500 Broening Highway Baltimore, Maryland 21224

Dear Secretary Nishida:

The Environmental Protection Agency (EPA), Region III has reviewed the report "Total Maximum Daily Load (TMDL) documentation for Chlordane in Back River" which was submitted by the Maryland Department of Environment (MDE) on July 23, 1999. Pursuant to 40 CFR Section 130.7(d), EPA is approving the Back River TMDL with the following provision.

It is EPA's understanding that fish tissue collection and analysis for chlordane will start in 2000, and this data will be shared with EPA and U.S. Fish and Wildlife. If this future fish tissue data collection does not show a declining trend for chlordane, EPA would expect the state to conduct a source assessment for chlordane. If this assessment indicates that the TMDL needs revision, the state will need to address this issue.

The definition of Load Allocation (LA) at 40 CFR Section 130.2(g) states, in part, that "Load allocations are best estimates of the loading, which may range from reasonably accurate estimates to gross allotments, depending on the availability of data and appropriate techniques for predicting the loading." Further, a wasteload allocation (WLA), according to 40 CFR Section 130.2(h), is "The portion of a receiving water's loading capacity that is allocated to one of its existing or future point sources of pollution. WLAs constitute a type of water quality-based effluent limitation." In addition, a TMDL is defined at 40 CFR Section 130.2(I) as "The sum of the individual WLAs for point sources and LAs for nonpoint sources and natural background."

Thus, EPA has determined that the TMDL and technical report are consistent with the regulations and requirements of 40 CFR Section 130 (see enclosed Rationale for Approval). Pursuant to 40 CFR Sections 130.6 and 130.7(d)(2), the TMDL and the supporting documentation, should be incorporated into Maryland's current water quality management plan.

If you have any questions or concerns, please contact Thomas Henry at 215-814-5752.

Sincerely,

TARSA

OFFICE OF THE DIRECTOR

Jon M. Capacasa, Acting Director

Water Protection Division

Enclosure

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Decision Rationale

Total Maximum Daily Load for Chlordane in Back River

I. Introduction

This document will set forth the Environmental Protection Agency's (EPA) decision rationale for approving the Total Maximum Daily Load (TMDL) for chlordane in Back River submitted by the Maryland Department of the Environment (MDE) on July 23, 1999. Our rationale is based on information provided in the TMDL document to determine if the TMDL meets the following 8 regulatory requirements:

- A. The TMDLs are designed to implement applicable water quality standards.
- B. The TMDLs include a total allowable load as well as individual waste load allocations and load allocations.
- C. The TMDLs consider the impacts of background pollutant contribution.
- D. The TMDLs consider critical environmental conditions.
- E. The TMDLs consider seasonal environmental variations.
- F. The TMDLs include a margin of safety.
- G. The TMDLs have been subject to public participation.
- H. There is reasonable assurance that the TMDLs can be met.

II. Background and Summary

The Back River¹, which is fed primarily by Herring Run, Redhouse Run, and Stemmers Run, is a tidal estuary of the Chesapeake Bay. The watershed is approximately 15 miles long and 6 miles wide and is located on the western shore just north of the Baltimore Harbor. The watershed is largely residential with some industrial development along the lower end of Herring Run.

On February 5, 1986, The Maryland Department of Health and Mental Hygiene (MDHMH) issued a "Health Advisory" which limited the consumption of channel catfish and american eels from the Back River due to historical fish tissue sampling which indicated elevated levels of chlordane in those two species above the Fish and Drug Administration (FDA) Action Level. The most recently analyzed fish tissue data from 1987 indicates that levels of chlordane in catfish and eel still exceed the FDA Action Level. Consequently, the fish consumption advisory remains in place today. Based on this information, Maryland listed the Back River on the 1996 Clean Water Act (CWA) Section 303(d) list of water quality impaired waterbodies. While

¹ The Back River is listed on the Maryland 1996 Clean Water Act Section 303(d) list of impaired waters as basin segment 02130901 and is given low priority.

nutrients, suspended sediments and chlordane were identified as the substances causing the impairment, only chlordane is being addressed in this TMDL. It is EPA's understanding that this is one of several TMDLs being established by Maryland to facilitate the development of expertise in areas other than nutrient TMDLs. EPA expects that TMDLs of nutrients and sediments for the Back River will be developed in accordance with the schedule provided by Maryland on September 13, 1999. Likewise, multiple sources (point sources, nonpoint sources, and natural) are listed, however, there are no significant point sources of chlordane in the Back River and chlordane does not occur naturally in the environment.

The CWA at Section 303(d) and its implementing regulations require a TMDL to be developed for those waterbodies identified as impaired by the State where technology-based and other required controls did not provide for the attainment of water quality standards. The TMDL submitted by MDE is designed to attain acceptable levels of chlordane in the water column and sediments which will not cause bioaccumulation of chlordane by aquatic organisms to a level which would present a human health risk². Furthermore, this TMDL is designed to restore the designated uses³ of Back River and allow for the attainment of narrative water quality criteria⁴, both of which are currently not being met. Table 1 below summarizes the TMDL for Chlordane in the Back River.

Table 1, Chlordane TMDL summary (in ug/l)

Parameter	TMDL	WLA*	LAb	MOS ^e
Chlordane	0.00059	0	0.00059	implicit

- Maryland states that there are no significant point sources of chlordane in the Back River watershed.
- Maryland states that there are no overland runoff sources of chlordane to the Back River watershed and allocates the entire TMDL to in-situ estuary sediments.
- Maryland utilizes a numeric endpoint of 0.00059ug/l for chlordane, which is more stringent than EPA's CWA Section 304(a) recommended human health water quality criterion of 0.0022ug/l and results in an implicit margin of safety.

² Maryland has designated a risk level of 10⁻⁵, which translates into an increased probability for effects from cancer of 1 in 100,000.

³ The Code of Maryland Regulations at Sections 26.08.02.02(B) and 26.08.02.07(A) lists the designated uses of Back River as Use I- Water Contact Recreation and Protection of Aquatic Life.

⁴ The Code of Maryland Regulations at Section 26.08.02.03(B) states "The waters of this State may not be polluted by:.....(2) any material, including floating debris, oil, grease, scum sludge, and other floating materials attributable to sewage, industrial waste, or other waste in amounts sufficient to:.....(f) interfere directly or indirectly with designated uses;" or "(5) toxic substances attributable to sewage, industrial discharges, or other wastes in concentrations outside designated mixing zones, which:....(a) interfere directly or indirectly with designated uses, or (b) are harmful to human, plant, or aquatic life."

EPA notes that the TMDL of 0.00059ug/l is a concentration, as opposed to an actual mass load. This is acceptable because 40 CFR Part 130.2(I) states "TMDLs can be expressed in terms of either mass per time, toxicity, or other appropriate measure." Given the nature of the source and the type of waterbody, expressing the TMDL as a concentration is necessary (see discussion under critical conditions).

Maryland utilizes a method outlined in the Technical Basis for Deriving Sediment Quality Criteria for Nonionic Organic Contaminants for the Protection of Benthic Organisms by Using Equilibrium Partitioning (EPA-822-R-93-011) to determine the appropriate load allocation for in-situ Back River estuary sediments (see critical conditions section for discussion of EPT methodology). The governing equation, based on the Equilibrium Partitioning Theory (EPT), to determine the acceptable sediment concentration of chlordane (ASC) is:

$$ASC(ug/g \text{ sediment}) = K_p(L/kg \text{ sediment}) * FCV(ug/L) \times 0.001 \text{ kg/g}$$

where FCV = Final Chronic Value from water quality criteria

 K_p = partition coefficient = $C_s / C_d = f_{oc} * K_{oc}$

 C_s = sediment concentration

 C_d = pore water concentration

 f_{oc} = mass fraction of organic carbon for the sediment

 K_{oc} = partition coefficient for sediment organic carbon

The EPT methodology can also be used to determine the pore-water concentration of chlordane within the sediments. EPA recognizes that overlying water column concentrations can not be determined using this methodology, however, it is reasonable to assume that the overlying water column concentration will be less than the pore-water concentration, given that sediment is the dominant source (see critical conditions section for discussion of EPT methodology).

III. Discussion of Regulatory Conditions

EPA finds that Maryland has provided sufficient information to meet all of the 8 basic requirements for establishing a chlordane TMDL for Back River. EPA therefore approves the TMDL of chlordane in Back River. Our approval is outlined according to the regulatory requirements listed below.

1) The TMDL is designed to implement the applicable water quality standards.

Maryland does not currently have a numeric water quality criterion for chlordane. Therefore, Maryland interprets its General Water Quality Criteria⁵ to establish a numerical endpoint of 0.00059ug/l of chlordane for the TMDL such that designated uses of the Back River

⁵ The Code of Maryland Regulations at Section 26.08.02.03B.

will be restored. In addition, this endpoint will comply with the applicable narrative water quality criteria. It should be noted that this numerical endpoint is more stringent than EPA's recommended water quality criteria for chlordane, pursuant to CWA Section 304(a), of 0.0022ug/l. The value of 0.00059ug/l used by Maryland represents EPA's previous CWA Section 304(a) recommendation prior to reevaluation using information from the Integrated Risk Information System (IRIS) on February 7, 1998. EPA published its new 304(a) human health water quality criteria recommendation for chlordane of 0.0022ug/l in the *Federal Register* Notice (Volume 63, Number 237) of December 10, 1998. Since the endpoint for this TMDL is more stringent than current recommended human health water quality criteria, EPA believes Maryland's interpretation of its narrative water quality standards is adequate and conservative.

Chlordane⁶ has been classified as a probable human carcinogen (B2)^A (see endnotes) and is also a known Bioaccumulative Chemical of Concern (BCC) which means that even at very low concentrations these chemical have the propensity to accumulate in aquatic organisms to levels which could adversely affect human health if consumed. As previously mentioned, Maryland has identified an endpoint of 0.00059ug/l of chlordane as the basis of the TMDL. This number is more stringent than our CWA Section 304(a) water quality criteria recommendation for chlordane of 0.0022ug/l. Our water quality criterion recommendation represents ambient pollutant concentrations in the water column that is not likely to pose a significant risk of cancer to the exposed human population. More specifically, the human health criterion relies on an assessment of risks related to surface water exposure which includes exposure due to ingestion of water and contaminated fish and shellfish. In addition, this water quality criterion or endpoint is more stringent than the freshwater Criterion Maximum Concentration (Acute) and the Criterion Continuos Concentration (Chronic). Thus, the endpoint chosen by Maryland will ensure that the TMDL adequately protects aquatic life from short-term, long-term, and bioaccumulative effects and human health from adverse effects due to consumption of potentially contaminated aquatic organisms and water.

2) The TMDL includes a total allowable load as well as individual waste load allocations and load allocation.

As previously mentioned, Maryland establishes a concentration of 0.00059ug/l as the TMDL using the EPT methodology. Due to Maryland's determination (see Wasteload Allocations and Load Allocations sections below for discussion regarding this determination) that sediment is the dominant source of chlordane to Back River, the entire concentration is given to the load allocation, specifically the in-situ estuary sediments. Within the context of the EPT methodology, achieving a pore-water concentration of 0.00059ug/l will prevent adverse effects to human health and aquatic life, including bioaccumulation. Furthermore, given that the EPT approach is based on the assumption of equilibrium partitioning, achieving this pore-water

⁶ Chlordane is broad spectrum insecticide of the group polycyclic chlorinated hydrocarbons called cyclodiene insecticides. Ambient Water Quality Criteria for Chlordane, 1980, EPA 440/5-80-027.

concentration will also ensure that sediment concentrations will not cause adverse impacts to human health or aquatic life. While EPA realizes that this model only predicts pore-water concentrations, we believe it is reasonable to assume that the overlying water column concentration will be similar or less than the pore-water concentration thus providing for the attainment of water quality standards and the lifting of the fish consumption advisory. Maryland's approach is outlined below:

I) Determine the log K_{∞} for chlordane

Log
$$K_{\infty}$$
=0.00028 + 0.983 (log K_{ow})
Log K_{∞} = 0.00028 + 0.983 (5.54⁷)
Log K_{∞} = 5.45
 K_{∞} = 279,000 L/kg

ii) Determine the acceptable sediment concentration of chlordane

ASC(ug chlordane/g sediment) =
$$K_p(L/kg \text{ sediment}) * FCV(ug/L) \times 0.001 \text{ kg/g}^8$$

where FCV = Final Chronic Value or numerical TMDL endpoint =
$$0.00059ug/L$$

 K_p = partition coefficient = $C_s / C_d = f_{\infty} * K_{\infty}$

 C_s = sediment concentration = 1.12 ng chlordane /g sediment (dry weight)

 C_d = pore water concentration

 f_{∞} = mass fraction of organic carbon for the sediment = 0.0506

 K_{∞} = partition coefficient for sediment organic carbon = 279,000 L/kg

ASC (ug/g sediment) =
$$(0.0506)*(279,000L/kg)*(0.00059ug/L)$$

= 8.33 ug/kg or 8.33 ng/g

The current sediment quality concentration of 1.12 ng chlordane/g sediment is well below the predicted acceptable sediment concentration for chlordane of 8.33 ng/g, which is designed to prevent adverse impacts to human health and aquatic life.

iii) Determine current pore-water (interstitial) concentration of chlordane

⁷ EPA Graphical Exposure Modeling System (GEMS). CLOGP Computer Program, Version PC 1,2, August 1, 1986.

⁸ This conversion factor may become unnecessary if the units in the original equation are converted prior to being placed into the governing equation.

$$C_s / C_d = f_{oc} * K_{oc}$$

$$C_d = C_s / f_{oc} * K_{oc}$$

$$= 1.12 \text{ ug/kg} / (0.0506 \text{ g/g} * 279,000\text{L/kg})$$

$$= 0.0000793 \text{ ug/L}$$

The current predicted pore-water (interstitial) concentration of chlordane is at least 1 order of magnitude less than the endpoint of the TMDL. While it may seem to imply that the designated uses and narrative water quality criteria of Back River are currently being met (thus invalidating the need for a TMDL), that determination would need to be based on fish tissue analysis indicating that recent fish tissue samples are below the FDA Action Level. Certainly, recent sediment data samples appear to indicate that exposure of aquatic organisms and the overlying water column to chlordane from sediments and pore-water are below levels which could adversely impact aquatic life and human health, however, determining the effect on the aquatic/biological system to this level of exposure will take a certain amount of time. This period of recovery depends on many factors including the depuration rate of chlordane for aquatic organisms in the Back River. If fish tissue data was available to demonstrate that chlordane was not bioaccumulating to levels which could adversely impact human health and violate the designates uses and narrative water quality criteria of back River, it could be used to demonstrate that a TMDL was not needed for this waterbody. In the absence of such data, Maryland is obligated, under CWA Section 303(d), to establish a TMDL of chlordane for the Back River.

A. Wasteload Allocations

Maryland states that there are point source discharges within the Back River estuary, however, none of these point sources are expected to contribute significant amounts of chlordane. The Back River Wastewater Treatment Plant (WWTP) discharge was sampled in 1989 and again in 1998 and produced no detectable amounts of chlordane (Detection level of 0.086ug/l). Furthermore, chlordane sales have been banned since April 15, 1988 and the product registration was canceled in 1993. Therefore, Maryland has indicated a Wasteload Allocation of zero.

B. Load Allocations

The load allocation is the amount of pollutant that reaches the waterbody through nonpoint source contributions as well as any natural background levels in the waterbody itself. Chlordane is a man-made organochlorine compound and does not exist naturally in the environment. No allocation of chlordane is made to natural background contributions.

While chlordane could be introduced to a waterbody through nonpoint source runoff from

⁹ Depuration is the loss of a substance from an organism as a result of any active or passive process.

overland flow, Maryland provides data from an unpublished 1994 study¹⁰ in which 7 of the 10 samples taken from Back River watershed stations indicated chlordane levels that were below detection level or less than the level of quantification. Only one sample of 0.08ug/l indicated levels of chlordane which were moderately higher than the quantification level (0.02ug/l).

Once in a waterbody, chlordane will both rapidly adsorb to sediments and volatilize. The majority of chlordane, however, probably enters water as runoff from urban and agricultural soils and, hence, is adsorbed to particulates before entering a waterbody¹¹. Furthermore, chlordane adsorbs almost completely to sediments in water sediment systems over a period of about 6 days¹². While Huang (1970)¹³ found that chlordane volatilizes reasonably rapidly from water perhaps indicating that volatilization kinetics may proceed faster than adsorption kinetics, monitoring data indicates that sediment concentrations of chlordane are much higher than the overlying water, suggesting that volatilization from water may not be as fast as predicted.¹⁴

Based on the available information, Maryland allocates the entire load allocation to insitu estuary sediments. Table 2 below is a summary of the load allocation.

Table 2, Load allocation summary (in ug/l)

Parameter 1	Load allocation
Chlordane	0.00059

^a The entire load allocation is attributed to in-situ estuary sediments.

3) The TMDL considers the impacts of background pollutant contributions.

This requirement is most applicable to naturally-occurring parameters. Chlordane is a man-made organochlorine pesticide which is not expected to occur naturally in the environment. Therefore, no background pollutant contribution is expected.

¹⁰ Maryland Department of the Environment unpublished 1994 urban stormwater runoff study (MDE draft August 1997).

¹¹ Toxicological Profile for Chlordane, Syracuse Research Corporation, Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, ATSDR/TP-89/06, December 1989.

¹² Oloffs PC, Albright LJ, Szeto SY. 1972. Fate and Behavior of five chlorinated hydrocarbons in three natural waters. Can J Microbiol 18:1393-1398.

¹³ Huang JC. 1970. Fate of organic pesticides in the aquatic system. Eng Bull Purdue Univ Eng Ext Series, 449-457.

¹⁴ Supra see footnote 7

4) The TMDL considers critical environmental conditions.

EPA regulations at 40 CFR 130.7(c)(1) require TMDLs to take into account critical conditions for streamflow, loading, and water quality parameters. The intent is to ensure that the TMDL is protective of human health.

Critical conditions are important because they describe the factors that combine to cause a violation of water quality standards and will help in identifying the actions that may have to be undertaken to meet water quality standards.¹⁵ In specifying critical conditions in the waterbody, an attempt is made to use a reasonable "worst-case" scenario condition. Critical conditions are the combination of environmental factors (e.g., flow, temperature, etc.) that results in attaining and maintaining the water quality criterion and has an acceptably low frequency of occurrence. For example, stream analysis often uses a low-flow (7Q10) design condition as critical because the ability of the waterbody to assimilate pollutants without exhibiting adverse impacts is at a minimum. Given the lack of flow and other considerations within the estuary itself, consideration of the "traditional" critical conditions is not applicable.

Consideration of critical conditions within the context of this TMDL is based on the conclusion that the dominant source of chlordane is from in-situ estuary sediments. The critical condition then becomes based on the EPT, which assumes that chemicals such as chlordane (nonionic organic contaminants) will reach a partitioning equilibrium among three phases: lipids of biota (aquatic life); freely dissolved in the pore water; or sorbed to particulate organic carbon, which is a constituent of all sediments. The technical issues which EPT addresses, which are the varying bioavailability of chemicals in sediments and the choice of the appropriate biological effects concentrations, then become the specific critical conditions of this TMDL.

The condition of varying bioavailability deals with actual data which indicates that there is essentially no relationship between sediment chemical concentrations on a dry weight basis and biological effects. However, if the chemical concentrations in the pore water of the sediment are used (for chemicals that are not highly hydrophobic) or if the sediment chemical concentrations on an organic carbon basis are used, then the biological effects occur at similar concentrations (typically within a factor of two) for the different sediments. EPT assumes that the partitioning of chlordane between sediment-organic carbon and pore water is at equilibrium. Since the chemical activity (fugacity) of chlordane is the same at equilibrium from each phase, the effective chemical exposure concentration to the organism is the same regardless of the route

¹⁵ EPA Memorandum regarding EPA Actions to Support High Quality TMDLs from Robert H. Wayland III, Director, Office of Wetlands, Oceans, and Watersheds to the Regional Water Management Division Directors, August 9, 1999.

¹⁶ Di Toro et al., 1991, Annual Review, Technical Basis for Establishing Sediment Quality Criteria for Nonionic Organic Chemicals Using Equilibrium Partitioning, Environmental Toxicology and Chemistry, Vol 10, pp1541-1583.

of exposure¹⁷ (either from ingestion of sediment carbon or from the water-only exposure). This is an important component of the EPT theory which allows its application in quantifying an acceptable exposure concentration to the organism. Essentially, using the endpoint of 0.00059ug/l will ensure that aquatic organisms and the overlying water column are not exposed to concentrations of chlordane from pore-water or sediments which could cause adverse impacts.

The choice of the appropriate biological effects concentration relies on the determination that benthic species have a similar sensitivity to water column species to allow use of the Final Chronic Value (FCV), used for EPA's water quality criteria, to determine the appropriate chemical concentration to protect benthic organisms. The apparent equality between the effects concentration as measured in pore water an in water-only exposures supports using an effects concentration derived from water-only exposure.¹⁸

Maryland appropriately considers the bioavailability critical condition by using the octanol/water partition coefficient, K_{ow} , as determined by EPA (1986)¹⁹ and a regression equation²⁰ to determine the partition coefficient for sediment organic carbon. This value is then used in the determination of the partition coefficient, K_p , which is used in the governing equation.

Maryland also considers the appropriate biological effects concentration by using the TMDL endpoint of 0.00059ug/l in place of the FCV for chlordane. The value of 0.00059ug/l represents the previously recommended CWA Section 304(a) human health water quality criterion which is designed to prevent adverse impacts to human health through the ingestion of water or aquatic organisms. In addition, this value is more stringent than EPA's current 304(a) human health water quality criterion recommendation of 0.0022ug/l as well as both the criterion maximum concentration (CMC) of 2.4ug/l and the criterion continuos concentration (CCC) of 0.0043ug/l. Therefore, the TMDL is protective of both human health and aquatic life.

5) The TMDL considers seasonal environmental variations.

Seasonal variations involve changes in stream flow as a result of hydrologic and climatological patterns. In the continental United States, seasonally high flow normally occurs during the colder period of winter and in early spring from snowmelt and spring rains, while

¹⁷ Supra see footnote 15.

¹⁸ Supra see footnote 15.

¹⁹ Supra see footnote 7

²⁰ Supra see footnote 15. $\log_{10} K_{\infty} = 0.00028 + 0.983 \log_{10} K_{\text{ow}}$

seasonally low flow typically occurs during the warmer summer and early fall drought periods.²¹ Similar to consideration for critical environmental conditions, explicit consideration of seasonal variations in the traditional sense is not appropriate within the context of this TMDL.

6) The TMDL includes a margin of safety.

This requirement is intended to add a level of conservatism to the modeling process to account for any uncertainty. Maryland uses an implicit margin of safety by establishing an endpoint for the TMDL of 0.00059ug/l, which is more stringent than our current CWA Section 304(a) human health water quality criterion of 0.0022ug/l. EPA believes that this an acceptable MOS.

7) The TMDL has been subject to public participation.

Maryland provided an opportunity for public review and comment on the TMDL of Chlordane for Back River which extended from February 12, 1999 to March 15, 1999. Only one set of written comments were received by MDE. Those comments and responses were provided with the TMDL document.

8) There is reasonable assurance that the TMDL can be met.

There are essentially two options available to remedy the delivery of chlordane from insitu estuary sediments in the Back River. These two options are dredging and natural recovery/attenuation. Dredging could potentially cause resuspension of the contaminated sediments as well as cause possible habitat destruction. In addition, this option is very costly and not regarded as a viable option at this point. The only other option, natural recovery/attenuation, appears to be proceeding in the form of declining sediment concentrations of chlordane as indicated by recent observed data from Eskin²² (1996). Maryland is also proposing an iterative monitoring and evaluation process in the form of routine sediment and fish tissue monitoring, with occasional stream and water column samples. Maryland is proposing triennial monitoring of fish and surface sediments with yearly reevaluation regarding the sampling frequency.

²¹ Section 2.3.3 of the Technical Guidance Manual for Developing Total maximum Daily Loads, Book 2, Part 1 (EPA 823-B-97-002, 1997).

²² Eskin R.A., Rowland, K.H., Alegre, D.Y. 1996. "Contaminants in Chesapeake Bay Sediments 1984-1991", Chesapeake Bay Program, CBP/TRS 145/96.

A. Hazard identification is a qualitative determination of how likely it is that a chemical will increase the incidence of cancer. It involves a judgement in the form of a weight-of-evidence classification of the likelihood that the chemical is a human carcinogen and includes the type of data (human, animal, supporting) used as the basis of the classification. This judgement is made independently of consideration of chemical potency.

Weight of Evidence

Group A-Human Carcinogen

Group B-Probable Human Carcinogen Group C-Possible Human Carcinogen Group D-Not Classifiable

Group E-Evidence of Noncarcinogenicity

Group 1-Human Data Group 2-Animal Data Group 3-Supporting Data(e.g. DNA damage, metabolism